MAR 1 9 2009

510(k) Summary of Safety and Effectiveness

K090481

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
November 20, 2008

Submitter's Information: 21 CFR 807.92(a)(1)

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Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	DEMASQ Imaging Software Device™
Common Name:	Picture Archiving Communications System
Classification Name:	system, image processing, radiological
Product code:	LLZ
Device Classification:	892.2050

Predicate Device: 21 CFR 807. 92(a)(3)

510(k) Number	K052545	K071894
Device Classification Name	system, image processing, radiological	system, image processing, radiological
Regulation Number	892.2050	892.2050
Device Name	INFINITT G3 PACS	XEBRA DICOM IMAGE BROWSER
Applicant	INFINITT CO., LTD.	HX TECHNOLOGIES, INC.
Product Code	LLZ	LLZ
Decision Date	11/08/2005	08/16/2007

Device Description: 21 CFR 807 92(a)(4)

DEMASQ Imaging Software Device™ (DISD) is a user network and or a web-based PACS DICOM viewing software running on an IBM Compatible PC with a Windows 98 SE, Windows NT 4.0 (with SP 5 or later), XP or Vista operating system.

DISD is adapted for, storing, processing, routing and report generating. DISD supports the DICOM standard. To assist interpretation a user-friendly interface will allow the end-user to color, crop, zoom, rotate, measure and save the image. Images can be saved to a desktop or network as a standard file format.

DISD allows users to take full advantage of the radiographic images from digital X-ray and various modalities in order to obtain invaluable mission critical diagnostic data and images.

510(k) Summary of Safety and Effectiveness

Indications for Use: 21 CFR 807 92(a)(5)

DEMASQ Imaging Software Device™ is a software device that receives medical images and data from various imaging sources (including but not limited to CT, MR, US, RF units, computed and direct radiographic devices, and secondary capture devices, (scanners, imaging gateways or imaging sources). Images and data can be stored, communicated, processed and displayed within the system or across computer networks at distributed locations.

Only pre-processed DICOM for presentation images can be interpreted for primary image diagnosis in mammography.

Lossy compressed Mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA. Typical users of this system are trained professionals, e.g. physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics: 21 CFR 807 92(a)(6)

DEMASQ Imaging Software Device™ is a software device that does not contact the patient, nor does it control any life sustaining devices.

A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

DEMASQ Imaging Software Device ™ and its predicates have essentially the same technological characteristics.

The predicate devices and the new device are software PACS for use in medical image acquisition, management, manipulation, and distribution. All systems have been developed to replace traditional film handling in radiology.

The new device and predicate devices are substantially equivalent in the areas of technical characteristics, general function, application, and intended use.

The predicate device and the new device include the following similar features and functionality:

- Advanced reviewing features as contrast adjustments, magnification and more.
- Evaluation of general parameters such as pixel values and measurements of distances and angles in the images.
- Possibility of remote diagnoses through transmission via public or private telecommunications network (including the Internet) of an examination.
- Image data acquisition based on Ethernet communication standard with TCP/IP file transfer protocol and DICOM 3.0 radiology image file standards
- A user interface using Microsoft Windows operating systems.
- Internal handling of images in DICOM 3.0 format.
- On-line help system

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for DEMASQ Imaging Software Device™ contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The subject device has been designed and will be delivered in accordance with the voluntary standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 2009

DEMASQ Limited
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K090481
Trade/Device Name: DEMASQ Imaging Software Device™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 20, 2009
Received: February 24, 2009

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090481

Device Name: DEMASQ Imaging Software Device™

Indications for Use:

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Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090481